Federal Advisory Committee (FAC) Membership Balance Plan

(1) FEDERAL ADVISORY COMMITTEE NAME

State the legal name of the FAC

Technical Electronic Product Radiation Safety Standards Committee

(2) AUTHORITY

Identify the authority for establishing the FAC

The Technical Electronic Product Radiation Safety Standards Committee is a permanent statutory committee established pursuant to the provisions of the Radiation Control for Health and Safety Act (21 USC 360kk) and is also governed by the provisions of Pub.L. 92-463, as amended (5 USC App. 2), which sets forth standards for the formation and use of advisory committees.

(3) MISSION/FUNCTION

Describe the mission/function of the FAC

This Committee provides advice and consultation to the Commissioner of Food and Drugs on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products, and may recommend electronic product radiation safety standards to the Commissioner for consideration.

(4) POINTS OF VIEW

Based on understanding the purpose of the FAC,

- (a) describe the process that will be used to ensure the committee is balanced, and identify the categories (e.g. individual expertise or represented interests) from which candidates will be considered;
- (b) consider identifying an anticipated relative distribution of candidates across the categories; and
- (c) explain how a determination was made to appoint any individuals as Special Government Employees or Representative members

The Committee consists of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of science or engineering applicable to electronic product radiation safety. Members will be invited to serve for overlapping terms of up to four years. Terms of more than two years are contingent upon the renewal of the Committee by appropriate action prior to its expiration.

The core of voting members will include five members selected from governmental agencies, including State and Federal Governments, five members from the affected industries, and five members from the general public, of which at least one shall be a representative of organized labor. A quorum shall consist of 10 members, of which at least 3 shall be from the general public, 3 from the government agencies, and 3 from the affected industries.

A review of a potential member's curriculum vitae, list of publications and committee affiliations is conducted to determine points of view and committee balance. The charter is renewed every two years to determine needed expertise based on upcoming and projected committee topics. It is expected that balance is not static, and the expertise or experience relevant to the mission/function of this committee may change over time, depending on the work of the committee.

As governed by 21 U.S.C. 360kk(f)(2) "payments to members of the Committee who are not officers or employees of the United States pursuant to subsection (c) of section 210 of title 42 shall not render members of the Committee officers or employees of the United States for any purpose." Thus, members of the committee who are not regular Government employees, such as the industry and public members, are appointed outside of the civil service authority as special consultants (42)

(5) OTHER BALANCE FACTORS

List any other factors your agency identifies as important in achieving a balanced FAC

Appointments shall be made without discrimination on the basis of age, race, gender, sexual orientation, HIV status, and cultural, religious, or socioeconomic status. During the nomination process, the committee is reviewed in totality for balance with regard to geographic location and female and minority representation. A balanced committee is characterized by inclusion of the necessary knowledge, insight, and scientific perspective from the community or expertise area which the members serve.

(6) CANDIDATE IDENTIFICATION PROCESS

Summarize the process intended to be used to identify candidates for the FAC, key resources expected to be tapped to identify candidates and the key persons (by position, not name) who will evaluate FAC balance. The summary should:

(a) describe the process

(b) identify the agency key staff involved (by position, not name)

(c) briefly describe how FAC vacancies, if any, will be handled by the agency, and

(d) state the membership term limit of FAC members, if applicable

FDA staff involved in advisory committee activities are responsible for recruiting members to fill vacancies. A Federal Register Notice announcement is published soliciting nominations for vacancies in the coming year. Agency Designated Federal Officers and Office/Division Directors are responsible for the initial review and evaluation of prospective members for competence and membership suitability. All individuals interested in serving as members should have the background, education, and experience commensurate with function of the committee and the advice it renders. Scientific and technical competence is critical. Special attention is also paid to leadership qualities. Whenever possible, nominees are acknowledged experts in their fields whose credibility is beyond question. All nominees should have demonstrated skills in critical evaluation of data and communication skills necessary to promote efficient and effective deliberation.

Membership structure is outlined in the committee charter that describes the desired scientific expertise as well as needed individuals from the general public, government agencies, and the affected industries.

The responsible office seeks qualified candidates from relevant professional, scientific, and medical societies, medical and other professional schools, academia, government agencies, industry and trade associations, and professional organizations likely to have knowledge of women and minority candidates. Consideration is given to the use of vacancy announcements in nationally recognized medical and scientific journals. Nominations are also sought from appropriate staff within the Agency as well as from current and former members. A computerized database established by the Agency is also utilized to identify potential committee members.

Designated Federal Officers, Division/Office Directors, and the Advisory Committee Oversight and Management Staff work to see that committees are balanced. Nominations are to be requested from all geographic locations within the United States or its territories. Anyone may nominate an individual, including them self, for committee membership.

The responsible office must keep abreast of term ending dates and have appointments to fill vacancies ready in advance. Approximately nine to twelve months before a vacancy is to occur, the Designated Federal Officer works with appropriate officials to discuss candidates and mechanisms to seek additional nominations. The Designated Federal Officer is responsible for ensuring that vacancies are filled promptly, terms remain staggered as provided in the committee

charter, and, to the extent possible, full slates of nominees are submitted for vacancies.

Members will be invited to serve for overlapping terms of up to four years. If appointed to fill an unexpected vacancy due to retirement or otherwise, the newly appointed member is to serve only the remainder of the four-year term. Term stratification exists with the goal to avoid no more than 33% of members rotating off the committee at one time. This limits frequent turnover, maintains expertise and experience, and brings new perspectives to the committee.

The Commissioner or designee makes the final decision about who will serve on the committee.

(7) SUBCOMMITTEE BALANCE

Subcommittees subject to FACA* should either state that the process for determining FAC member balance on subcommittees is the same as the process for the parent FAC, or describe how it is different *This is relevant to those agencies that require their subcommittees to follow all FACA requirements.

N/A

(8) OTHER

Provide any additional information that supports the balance of the FAC

The advisory committee system enables the FDA to secure the professional expertise and vital support necessary to accomplish its mission and maintain public trust. The committees consist of individuals possessing recognized expertise and judgment in specific fields. Members have the training and experience necessary to evaluate information objectively and to interpret its significance under various, often controversial, circumstances.

(9) DATE PREPARED/UPDATED

Insert the actual date the Membership Balance Plan was initially prepared, along with the date(s) the Plan is updated

Shanika Craig, Designated Federal Officer 11/07/2016

Shanka Cring